



Make it Work!: Breyer on Patents in the Life Sciences

Citation

I. Glenn Cohen, Make it Work!: Breyer on Patents in the Life Sciences, 128 Harv. L. Rev. 418 (2014).

Published Version

http://cdn.harvardlawreview.org/wp-content/uploads/2014/11/vol128_breyer_tribute.pdf

Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:16460370>

Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Open Access Policy Articles, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#OAP>

Share Your Story

The Harvard community has made this article openly available.
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

MAKE IT WORK!
BREYER ON PATENTS IN THE LIFE SCIENCES

I. Glenn Cohen¹

Professor of Law

*Faculty Co-Director, Petrie-Flom Center for Health Law Policy,
Biotechnology, and Bioethics*

Like Tim Gunn, the avuncular advisor to aspiring designers on reality TV's *Project Runway*, if Justice Breyer had a slogan, it would be "Make it work!" The idea of the law as useful—as a way to solve problems—runs through his many writings, whether opinions, articles, or books. As he put it in his confirmation testimony before the Senate:

I believe that the law must work for people. The vast array of Constitution, statutes, rules, regulations, practices and procedures, that huge vast web, has a single basic purpose. That purpose is to help the many different individuals who make up America—from so many different backgrounds and circumstances, with so many different needs and hopes.²

This focus on making things work—making sure the train runs on time—is exemplified often in Justice Breyer's questions at oral argument. For example, in *Norfolk & W. Ry. Co. v. Hiles*,³ a case about the occupational injuries of railroad workers who connect one rail car to another, Justice Breyer let the railroad's advocate know that "my law clerk found" a device in "the Car and Locomotive Cyclopedia for 1974" that could make the task safer, noting that "they have four pictures."⁴

Sometimes Justice Breyer's tendency to try to make the law work, to be practical rather than adversarial, produces some surreal moments. One of my favorite such colloquies occurred during the severability portion of the oral argument in *NFIB v. Sebelius*.⁵ In this part of the oral argument,

the Justices confronted what to do about the huge number of programs contained in the more than one thousand pages of the Affordable Care Act should they strike down the individual mandate portion. In a colloquy with Deputy Solicitor General Edwin Kneedler, who argued for the government in favor of severability, and similar to one he had earlier with Paul Clement, who argued for the challengers to the law, Justice Breyer asked:

JUSTICE BREYER: I don't think it's not
24 uncommon that Congress passes an act, and then there are
25 many titles, and some of the titles have nothing to do
45
1 with the other titles. That's a common thing. And
2 you're saying you've never found an instance where they
3 are all struck out when they have nothing to do with
4 each other.
5 My question is, because I hear Mr. Clement
6 saying something not too different from what you say.
7 He talks about things at the periphery. We can't reject
8 or accept an argument on severability because it's a lot
9 of work for us. That's beside the point. But do you
10 think that it's possible for you and Mr. Clement, on
11 exploring this, to—to get together and agree on—
12 (Laughter)
13 JUSTICE BREYER:—I mean on—on a list
14 of things that are in both your opinions peripheral,
15 then you would focus on those areas where one of you
16 thinks it's peripheral and one of you thinks it's not
17 peripheral. And at that point it might turn out to be
18 far fewer than we are currently imagining. At which
19 point we could hold an argument or figure out some way
20 or somebody hold an argument and try to—try to get
21 those done.
22 Is—is that a pipe dream or is that a—
23 MR. KNEEDLER: I—I—I just don't think
24 that is realistic. The Court would be doing it without
25 the parties, the millions of parties.

In a world where every litigant was as committed to “make it work” as Justice Breyer, this approach would represent the ideal way forward on

the complex severability question the Court ultimately was able to duck. And while Breyer recognized it might have been a “pipe dream,” what a lovely dream it was. It was the kind of dream that animates his worldview, and this worldview is quite evident in Justice Breyer’s patent opinions—the subject of this tribute.

The second defining characteristic of Justice Breyer’s approach to the world that is evident in his opinions is his commitment to getting things right based on evidence and expertise. As Linda Greenhouse poetically put it, Justice Breyer’s “fundamental challenge—I am tempted to call it his tragedy, but I hesitate to ascribe dark emotions to this optimistic man—to navigate as an Enlightenment Justice in an unenlightened period of Supreme Court history, a counter-factual age when ideology routinely trumps evidence-based decision-making.”⁶

This element is also evident in Justice Breyer’s work in patent law. In *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.* (“*LabCorp*”),⁷ Justice Breyer (joined by Justices Souter and Stevens) took the unusual step of dissenting from the Court’s dismissal of certiorari. In so doing, he set out the legal theory that would ultimately become the Court’s in its subsequent forays into patentable subject matter in the biosciences, culminating in this year’s decision on gene patenting.

The case involved the amino acid known as homocysteine. Doctors have known for at least half a century that high homocysteine levels were associated with serious health problems, but it was the patent holders who determined the pathway: high levels of total homocysteine were signs of folic acid and vitamin B12 deficiencies. While it was well-established that these deficiencies led to health problems—pregnant women are routinely warned of spina bifida in their babies if they have too little folic acid—actually measuring folic acid and B12 in a patient was difficult. Measuring total homocysteine levels, by contrast, was quite easy, and so the association between high homocysteine levels and these deficiencies produced a useful tool for clinical practice.⁸

The patent holder, Metabolite, licensed its invention to LabCorp, permitting it to use the tests described in the patent in return for a 27.5%

share of related revenues, with the agreement permitting LabCorp to terminate the arrangement if “a more cost effective commercial alternative is available *that does not infringe a valid and enforceable claim of*” the patent.⁹ Eventually LabCorp decided to switch to using, in some instances, one of Metabolite’s competitors that had developed a test, and refused to pay royalties on its use of these other tests.¹⁰ Metabolite sued for patent infringement and breach of licensing agreement. As Justice Breyer put it, their theory was *not* that using the competitor test

infringed the patent’s claims describing methods for testing for homocysteine. Instead, respondents relied on a broader claim not limited to those tests, namely, claim 13, the sole claim at issue here. That claim—set forth below in its entirety—seeks patent protection for:

“A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

“assaying a body fluid for an elevated level of total homocysteine; and

“correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.”

Claim 13, respondents argued, created a protected monopoly over the process of “correlating” test results and potential vitamin deficiencies. The parties agreed that the words “assaying a body fluid” refer to the use of any test at all, whether patented or not patented, that determines whether a body fluid has an “elevated level of total homocysteine.” And at trial, the inventors testified that claim 13’s “correlating” step consists simply of a physician’s recognizing that a test that shows an elevated homocysteine level—by that very fact—shows the patient likely has a cobalamin or folate deficiency. They added that, because the natural relationship between homocysteine and vitamin deficiency was now well known, such “correlating” would occur automatically in the mind of any competent physician.

On this understanding of the claim, respondents argued, LabCorp was liable for inducing doctors to infringe.¹¹

At trial, a jury found that LabCorp had infringed. The case made its way up to the Federal Circuit, which upheld the decision on infringement. The Supreme Court granted certiorari on the question “[w]hether a

method patent . . . directing a party simply to ‘correlat[e]’ test results can validly claim a monopoly over a basic scientific relationship . . . such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.”¹² The Court granted certiorari against the recommendation of the Solicitor General, who recommended denying certiorari because “the issues necessary to address the question had not been fully argued below.” The Solicitor General somewhat tartly added that “if this Court were to consider reevaluating almost a quarter-century of administrative practice and lower court jurisprudence, it should do so based on a full record.”¹³

Ultimately the Court decided to dismiss the case as improvidently granted—perhaps it was the pouring in of amici briefs, or perhaps it was the replacement of Justice O’Connor by Justice Alito on the Court, leading to a disappearing fourth vote for certiorari. But Justice Breyer wrote his dissent from this decision, and in so doing laid the groundwork for a line of jurisprudence on patentable subject matter.¹⁴

The opinion’s explanation of why the Court was wrong to dismiss the petition as improvidently granted was vintage Breyer—practical, not interested in adversarialism or wasting of time, taking note of when expertise can be useful, and extremely respectful of his colleagues on the other side. Notice how impersonal he makes it:

I can find no good practical reason for refusing to decide the case. The relevant issue has been fully briefed and argued by the parties, the Government, and 20 amici. The record is comprehensive, allowing us to learn the precise nature of the patent claim, to consider the commercial and medical context (which the parties and amici have described in detail), and to become familiar with the arguments made in all courts. Neither the factual record nor the briefing suffers from any significant gap. No party has identified any prejudice due to our answering the question. And there is no indication that LabCorp’s failure to cite § 101 [pertaining to patentable subject matter, the main issue he would address] reflected unfair gamesmanship.

Of course, further consideration by the Federal Circuit might help us reach a better decision. Lower court consideration almost always helps.

But the thoroughness of the briefing leads me to conclude that the extra time, cost, and uncertainty that further proceedings would engender are not worth the potential benefit.

Finally, I believe that important considerations of the public interest—including that of clarifying the law in this area sooner rather than later—argue strongly for our deciding the question presented now.¹⁵

That is,

[t]o fail to do so threatens to leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of health care while inhibiting its effective delivery.¹⁶

Further, at the opinion's end, we get an amazingly modest statement about the progression of the Court's jurisprudence and its interaction with Congress that could come from only Justice Breyer, with his deep respect and experience serving the other branches:

Even [if the analysis on the merits we have offered is] wrong, however, it still would be valuable to decide this case. Our doing so would help diminish legal uncertainty in the area, affecting a “substantial number of patent claims.” *See* Brief for United States as Amicus Curiae 12-14 (filed Aug. 26, 2005). It would permit those in the medical profession better to understand the nature of their legal obligations. It would help Congress determine whether legislation is needed. *Cf.* 35 U.S.C. § 287(c) (limiting liability of medical practitioners for performance of certain medical and surgical procedures).

In either event, a decision from this generalist Court could contribute to the important ongoing debate, among both specialists and generalists, as to whether the patent system, as currently administered and enforced, adequately reflects the “careful balance” that “the federal patent laws . . . embod[y].”¹⁷

But far from getting it wrong, Breyer's opinion gets it exactly right. It was long ago established by the Court that Section 101 of the Patent

Act “[e]xclude[s] from . . . patent protection . . . laws of nature, natural phenomena, and abstract ideas.”¹⁸ In a very precise and short couple of paragraphs, he ties this rule into the animating policy motivations of patent law in a way consonant with his leitmotif of “make it work”:

The justification for the principle does not lie in any claim that “laws of nature” are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes too much patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection. U.S. Const., Art. I, § 8, cl. 8.

The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.

Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten. One way in which patent law seeks to sail between these opposing and risky shoals is through rules that bring certain types of invention and discovery within the scope of patentability while excluding others. And scholars have noted that “patent law[’s] exclu[sion of] fundamental scientific (including mathematical) and technological principles” (like copyright’s exclusion of “ideas”) is a rule of the latter variety. W. Landes & R. Posner, *The Economic Structure of Intellectual Property Law* 305 (2003). That rule reflects “both . . . the enormous potential for rent seeking that would be created if property rights could be obtained in [those basic principles] and . . . the enormous transaction costs that would be imposed on would-be users.” *Id.*, at 305-06; *cf.* *Nichols v. Universal Pictures Corp.*, 45 F.2d 119, 122 (C.A.2 1930) (L.Hand, J.).

Thus, the Court has recognized that “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are . . . the

basic tools of scientific and technological work.” *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). It has treated fundamental scientific principles as “part of the storehouse of knowledge” and manifestations of laws of nature as “free to all men and reserved exclusively to none.” *Funk Bros.*, *supra*, at 130, 68 S. Ct. 440. And its doing so reflects a basic judgment that protection in such cases, despite its potentially positive incentive effects, would too often severely interfere with, or discourage, development and the further spread of useful knowledge itself.¹⁹

Breyer then masterfully goes from this general principle to the specific patent claim 13 in this case. While conceding that the precise boundaries of what is a “natural phenomenon” are fuzzy, he concludes that the patent in this case “is not at the boundary,” but instead that “claim 13 is invalid no matter how narrowly one reasonably interprets that doctrine.”²⁰ In a rhetorically powerful move that will prefigure the fight over gene patents and testing for the BRCA 1 breast cancer gene, Breyer characterizes claim 13 as providing “those researchers with control over doctors’ efforts to use that correlation to diagnose vitamin deficiencies in a patient,” creating a Manichaeian story of researchers and corporate patenting versus doctors and patients.²¹

Treating it as beyond cavil (and essentially conceded by the parties) that “the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a ‘natural phenomenon,’” he considers the patent holders’ claim “that the correlation is nonetheless patentable because claim 13 packages it in the form of a ‘process’ for detecting vitamin deficiency, with discrete testing and correlating steps.”²² While conceding that the fact that a process involves a natural phenomenon would not move it beyond the scope of patentable subject matter in and of itself, Justice Breyer can find nothing worthy of patent protection beyond the correlation here:

Claim 13’s process instructs the user to (1) obtain test results and (2) think about them. Why should it matter if the test results themselves were obtained through an unpatented procedure that involved the transformation of blood? Claim 13 is indifferent to that fact, for it tells the user to use any test at all. Indeed, to use virtually any natural

phenomenon for virtually any useful purpose could well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter. . . . At most, respondents have simply described the natural law at issue in the abstract patent language of a “process.” But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge. . . . One might, of course, reduce the “process” to a series of steps, e.g., Step 1: gather data; Step 2: read a number; Step 3: compare the number with the norm; Step 4: act accordingly. But one can reduce any process to a series of steps. The question is what those steps embody. And here, aside from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable “natural phenomenon,” and I can find nothing in claim 13 that adds anything more of significance.²³

For this reason, Justice Breyer concludes that claim 13 is not patentable subject matter.

What is the significance of the *LabCorp* opinion? In direct terms, to be frank, not very much. It was a dissent from the dismissal of certiorari as improvidently granted, it is not binding authority, and it could merely have found its way into the dustbin of Supreme Court orders. Indeed, one might ask, why bother?

But in fact, *LabCorp* proved crucial in at least three respects.

First, Justice Breyer’s description of the patent dilemma in the area of diagnostics (and, in fact, health care more generally) energized discussion among academics that is only now hitting its stride.²⁴ Indeed, the language he used is incredibly clear and readily understandable to those outside science and the law. This too is one of the goals Justice Breyer himself espoused in his writing and public talks: for the Court to talk to the people in a way they can understand.

Second, following (and relying on) his opinion, some judges in the Federal Circuit grew more skeptical about what constitutes patentable subject matter in the life sciences, while others remained somewhat recalcitrant, setting up a further Supreme Court correction I discuss below. One good example of a Federal Circuit Judge “getting the message” of

Justice Breyer's approach is Judge Moore's dissent in *Classen Immunotherapies, Inc. v. Biogen IDEC*,²⁵ which explicitly invoked the language and ideas of Justice Breyer's dissent to argue against patent eligibility of immunization schedules:

Having discovered a principle—that changing the timing of immunization may change the incidence of chronic immune-mediated disorders—Classen now seeks to keep it for himself. In the '283 patent, he accomplishes this goal by claiming the use of the scientific method to study the incidence of chronic immune-mediated disorders. This preempts the field of study, and prevents any investigation into any immunogen, known or unknown, and to any disease, known or unknown, over any period of time. Where, as here, a patent preempts an idea, a basic building block of science, within a field of study, the patent in practical effect is a patent on the idea itself. *Gottschalk*, 409 U.S. at 72, 93 S. Ct. 253.

The intent and effect of the Classen claims is clear: to keep others from exploring the same principle. "Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten." *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127 (2006) (Breyer, J., dissenting from dismissal of petition). Extending patent protection here would "severely interfere with, or discourage, development and the further spread of useful knowledge itself." *Id.* at 128. To wit, nobody else can search for new immunogens, for use of new immunizations, to treat either existing or currently unknown chronic immune-mediated disorders without infringing.

Finally, the opinion set the glidepath for the Court's subsequent decisions on patentable subject matter in the face of recalcitrance from *other* Federal Circuit judges.²⁶ Justice Breyer authored the unanimous decision for the Court in *Prometheus v. Mayo*,²⁷ which solidified and extended *LabCorp*'s approach as the law of the land. That case concerned a process for using the drug thiopurine to treat autoimmune diseases; specifically, different patients metabolize the drug differently and the patent holder determined that correlations between metabolite levels and a particular patient's dose were "too high, risking harmful side effects, or too low, and so likely ineffective."²⁸ The patent holders'

claims recite (1) an “administering” step—instructing a doctor to administer the drug to his patient—(2) a “determining” step—telling the doctor to measure the resulting metabolite levels in the patient’s blood—and (3) a “wherein” step—describing the metabolite concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, and informing the doctor that metabolite concentrations above or below these thresholds “indicate a need” to decrease or increase (respectively) the drug dosage.²⁹

Justice Breyer’s opinion for the Court continued the through line of *LabCorp* and easily found that “[t]he relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law” and was thus not patentable.³⁰ The Court answered no to the question “Do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?”³¹ Instead, the Court held that:

The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.³²

In so doing, Justice Breyer reined in the “machine-or-transformation” test for patentability that the Federal Circuit had been using, indicating that while that “test is an ‘important and useful clue’ to patentability, we have neither said nor implied that the test trumps the ‘law of nature’ exclusion.”³³ He also addressed the question, which has subsequently come up in the gene patent and other high-profile patent decisions, on the effect

on the life sciences industry, and the fear that a holding of no patentable subject matter would cripple innovation. Here Justice Breyer's emphasis on "make it work" and evidence and expertise come beautifully together with respect to the coordinate branches as he writes:

Prometheus, supported by several amici, argues that a principle of law denying patent coverage here will interfere significantly with the ability of medical researchers to make valuable discoveries, particularly in the area of diagnostic research. That research, which includes research leading to the discovery of laws of nature, is expensive; it "ha[s] made the United States the world leader in this field"; and it requires protection. Brief for Respondent 52.

Other medical experts, however, argue strongly against a legal rule that would make the present claims patent eligible, invoking policy considerations that point in the opposite direction. The American Medical Association, the American College of Medical Genetics, the American Hospital Association, the American Society of Human Genetics, the Association of American Medical Colleges, the Association for Molecular Pathology, and other medical organizations tell us that if "claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care." Brief for American College of Medical Genetics et al. as Amici Curiae 7; see also App. to Brief for Association Internationale pour la Protection de la Propriete Intellectuelle et al. as Amici Curiae A6, A16 (methods of medical treatment are not patentable in most of Western Europe).

We do not find this kind of difference of opinion surprising. Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements. At the same time, patent law's general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to

balance these considerations may differ from one field to another. See Bohannon & Hovenkamp, *Creation without Restraint*, at 98-100.

In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. *Cf.* 35 U.S.C. §§ 161-64 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.³⁴

The trajectory of *LabCorp* and *Prometheus* also set the table for last term's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*³⁵ The case had been remanded for reconsideration in light of *Prometheus*, but when the case came before the Court again, the Court followed the path Justice Breyer started with *LabCorp* and unanimously held (curiously, with Justice Thomas and not Justice Breyer writing) that Myriad's test for the BRCA 1 breast cancer gene failed the test for patentable subject matter (it was a "product of nature") as to the claims relating to isolated DNA but not as to its claims relating to complementary DNA (cDNA).³⁶

Justice Breyer has become *the* patent law judge on the Court. His dissent from dismissal of certiorari in *LabCorp* set the stage for the most important Supreme Court decisions for biotech and the life sciences in the past half century. Throughout it all, the "Breyer-ly" virtues shine through: practicality, a deep interest in and understanding of how things work in the real world, a consideration of expertise, modesty, and respect for the coordinate branches.



ENDNOTES

- 1 I thank W. Nicholson Price for helpful comments, and Ashwin Phatak for outstanding research assistance.
- 2 The Nomination of Stephen G. Breyer to be an Associate Justice of the Supreme Court of the United States: Hearings Before the S. Comm. on the Judiciary, 103d Cong. 18, 20-21 (1994) (statement of Stephen G. Breyer, Supreme Court Nominee).
- 3 516 U.S. 400 (1996).
- 4 Linda Greenhouse, *The Breyer Project: "Why Couldn't You Work This Thing Out?"*, 4 Charleston L. Rev. 37, 38 (2009) (citing Transcript of Oral Argument at 12, *Norfolk & W. Ry. Co. v. Hiles*, 516 U.S. 400 (1996) (No. 95-96), 1996 WL 13955).
- 5 132 S. Ct. 2566, 2607 (2012).
- 6 Greenhouse, *supra* note __, at 38-39.
- 7 548 U.S. 124, 127 (2006) (Breyer, J., dissenting from dismissal of certiorari).
- 8 See Robin Feldman, *A Conversation on Judicial Decision-Making*, 5 Hastings Sci. & Tech. L.J. 1, 10 (2013).
- 9 *LabCorp*, 548 U.S. at 128.
- 10 *Id.*
- 11 *Id.* at 133 (citations omitted).
- 12 *Id.* at 132.
- 13 Feldman, *supra* note at 8, at 11; Brief for the United States as Amicus Curiae at 19, *LabCorp*, 548 U.S. 124 (2006) (No. 04-607).
- 14 *Id.* at 133.
- 15 *Id.* at 133.
- 16 *Id.* at 138.
- 17 *Id.* at 139.
- 18 *Id.* at 126 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).
- 19 *Id.* at 126-28.
- 20 *Id.* at 134-35.
- 21 *Id.* at 135.
- 22 *Id.* at 135.
- 23 *Id.* at 135-38.

- 24 See, e.g., Note, *Diagnostic Method Patents and Harms to Follow-On Innovation*, 126 Harv. L. Rev. 1370, 1377 (2013) (“Justice Breyer’s dissent in *LabCorp* recited a litany of harms that might occur if the patent at issue remained in force, including that the patent may ‘force doctors to spend unnecessary time and energy to enter into license agreements,’ ‘divert resources from the medical task of health care to the legal task of searching patent files,’ and ‘raise the cost of health care while inhibiting its effective delivery.’ Yet these concerns are not specific to the *LabCorp* claims, and the problems presented by these particular patents are underexplored in the literature.”).
- 25 659 F.3d 1057 (Fed. Cir. 2011).
- 26 For example, in *Prometheus* itself, Judge Lourie of the Federal Circuit wrote: “In reaching its conclusion, the district court relied heavily on the opinion of three justices dissenting from the dismissal of the grant of certiorari in [*LabCorp*]. That dissent is not controlling law and also involved different claims from the ones at issue here.” *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009).
- 27 *Mayo Collaborative Servs., v. Prometheus Labs., Inc.*, 566 U.S.—, slip op. at 3, 132 S. Ct. 1289 (2012).
- 28 *Id.* at 1290.
- 29 *Id.* at 1290-91.
- 30 *Id.* at 1297.
- 31 *Id.*
- 32 *Id.* at 1298.
- 33 *Id.* at 1303.
- 34 *Id.* at 1304-05.
- 35 133 S. Ct. 2107 (2013). Full disclosure: I co-authored an amicus brief for Dr. Eric Lander, one of the world’s preeminent gene scientists, that was extensively discussed at oral argument by Justice Breyer and the other Justices. That amicus brief urged the Court to adopt the path it took, so I am hardly a disinterested writer.
- 36 See generally *id.*

